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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,735	05/18/2000	Lieven DeVeylder	2283/301	1507

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 10/22/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/574,735

Applicant(s)

DEVEYLDER ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,7-25,27-31 and 36-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5,7-25,27-31 and 36-57 is/are rejected.
- 7) ☒ Claim(s) 53 and 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed August 13, 2002, paper no.25, has been entered.

Claims 1, 3-4, 6, 26, 32-35 and 58-59 are cancelled.

Claims 2, 5, 7, 11-12, 14-15, 17-19, 21, 25, 27-31, 36, 46 and 48-57 are newly amended.

Claims 2, 5, 7-25, 27-31 and 36-57 are pending.

The amendments to the specification have not been entered as a marked up version of the specification amendments was not included in the response filed August 13, 2002.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Specification

The specification remains objected to because the amendments to the specification have not been entered as a marked up version of the specification amendments was not included in the response filed August 13, 2002.

Claim Objections

The objection to claims 46 and 52 is withdrawn in light of the amendment of claims 46 and 52.

Claims 53-54 remain objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The rejection of claims 52-54 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn in light of the fact that claims 52-54 recite the CKI sequences.

Claims 2, 5, 7-25, 27-31, 36-51 and 55-57 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed April 9, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicants argue that a sufficient showing of written description can be made in different ways, such as by an actual reduction to practice, which Applicants have done with respect to SEQ ID NO:1 (reply pages 10-11). Applicants argue that with respect to the other species of CKIs encompassed by the rejected claims but not actually reduced to practice, Applicants may use other indicia to show possession of the claimed invention. Applicants point out that the claims as presently amended recite "[a] cyclin dependent kinase inhibitor (CKI) which interacts with CDC2a", and argue that the claims as amended are fully supported by the written description as indicated in the written description guidelines, since the disclosure

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describes the relevant identifying characteristics recited in the claims (binding to CDC2a) coupled with a known or disclosed correlation between function and structure. (reply pages 11-12). Additionally, with respect to the cited reference of Nakayama et al., Applicants argue that because there are no significant homologies between the CKIs disclosed by Applicants and the CKIs disclosed by Nakayama et al. except for the carboxy terminal end, Nakayama et al. is not relevant to the description of the methods and compositions of the instant invention (reply page 13).

Recitation that the CKI interacts with CDC2a does not overcome the written description rejection, as a correlation between a particular structural domain of a CKI and the interaction with CDC2a is not known or disclosed. The correlation between a particular structural domain of a CKI and the function of altering growth characteristics in a plant is also not known or disclosed. Additionally, the cited reference of Nakayama et al. is relevant to the description the instant invention insofar as Nakayama et al. teach that cyclin-dependent kinase inhibitors may exhibit structural and functional differences as well as similarities, such that one must describe in some manner the structural domains of CKIs that are required to achieve a desired effect.

Claims 2, 5, 7-25, 27-31 and 36-57 remain rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for a method of decreasing cyclin-dependent kinase activity in *Arabidopsis* plants which comprises introducing into a plant a nucleotide sequence of SEQ ID NO:1 encoding the homologous cyclin-dependent kinase inhibitor ICK2 of SEQ ID NO:2, wherein said method increases the level of ICK2 in a cell, increases plant cell size in petals leaves and stems, decreases cell number in a plant, increases leaf serration, increases the

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size of stomata, reduces petal size, reduces leaf veination, decreases endoreduplication and ploidy level in mature leaf cells, and reduces seed size, compared to wild type plants, does not reasonably provide enablement for methods of altering growth characteristics in plants which comprise introducing into a plant a nucleotide sequence encoding a cyclin-dependent kinase inhibitor, wherein said method modifies plant cell size, modifies cell number in a plant, alters leaf shape, alters leaf size, increases gas exchange and photosynthesis, alters tissue or organ shape or size, alters leaf veination, facilitates the transition from the mitotic cycle to G1 arrest, alters seed size, or alters seed shape, compared to wild type plants, for the reasons of record set forth in the office action mailed April 9, 2002.

Applicant's arguments filed August 13, 2002, have been fully considered but they are not persuasive.

Applicants point out that the method exemplified in the specification utilizes the CaMV 35S promoter, which is a strong constitutive promoter. As a consequence, expression of CKIs under the control of the CaMV 35S promoter results in plants having many altered growth characteristics, demonstrating that CKIs may be used to alter growth characteristics in plants, and specific growth modification may be manipulated according to the choice of promoter. With respect to methods that encompass both increasing and decreasing specific phenotypic characteristics, Applicants argue that one skilled in the art would understand from the teachings provided in the specification that the opposing characteristics are obtained depending on whether the CKI gene is upregulated or downregulated (reply page 15).

The Office does not dispute that the method exemplified in the specification results in transgenic plants having more than one altered growth characteristics, but the Office maintains

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that this does not mean that the invention is enabled for the use of a CKI to alter any plant growth characteristic in any way. Furthermore, while specific growth modification may be manipulated according to the choice of promoter, specific growth modification will still be limited to those cells and tissues in which CKI has been shown to affect growth. Finally, with respect to methods that encompass both increasing and decreasing specific phenotypic characteristics, while one skilled in the art would understand that opposing characteristics may be obtained by upregulating or downregulating respectively the expression of a particular nucleic acid, the claims are not limited to methods that employ upregulation or downregulation to achieve specific opposing characteristics.

In response to the Examiner's objection that the rejected claims are directed to plants in which any growth characteristic is altered in any way, Applicants argue that the claims are limited to alteration of growth characteristics that are due to the introduction into the plant of a gene encoding CKI which interacts with CDC2. Applicants point to the submitted reference of Exhibit A, which describes additional CKIs, isolated following the methods taught in the specification, which interact with CDC2a. Exhibit A teaches that expression of CKI3 in transgenic plants results in the same leaf phenotypes as taught by the present application. Applicants also point to the submitted reference of Exhibit B, which teaches that when overexpressed in transgenic plants, all CKI proteins which interact with CDC2a result in the same phenotype (reply page 16). Applicants point to the submitted reference of Exhibit A, which describes additional CKIs, isolated following the methods taught in the specification, which interact with CDC2a. Exhibit A teaches that expression of CKI3 in transgenic plants results in

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the same leaf phenotypes as taught by the present application. Applicants also point to the submitted reference of Exhibit B, which teaches that when overexpressed in transgenic plants, all CKI proteins which interact with CDC2a result in the same phenotype (reply page 16).

The Office maintains that while the claims may be limited to the introduction into the plant of a gene encoding CKI which interacts with CDC2, the claims are not limited to the specific alteration of specific growth characteristics that are due to the introduction into the plant of a gene encoding CKI which interacts with CDC2. Claim 2, for example is directed to a method for "controlling or altering growth characteristics in a plant". Since claim 2 does not specify what growth characteristics are altered or controlled, or in what way the characteristics are altered or controlled, claim 2 encompasses the control or alteration of any growth characteristic. Applicants have not demonstrated that expression of a CKI which interacts with CDC2 would control or alteration of any growth characteristic. Given that Applicants expressed a CKI under the control of a constitutive promoter that would presumably allow for CKI expression at all times and in all tissues, the specification only supports the enablement of the specific alterations and characteristics exemplified. The submitted references of Exhibits A and B support this conclusion as neither reference teaches changes in characteristics other than those exemplified in the specification.

Applicants further argue that the cited references of Riou-Khamlichi et al. and Cockcroft et al. are not relevant to the expression of CKIs in transgenic plants, as the teachings of the references are directed to the expression of Cyclin D proteins in transgenic plants (reply page 17).

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The Office acknowledges that the cited references of Riou-Khamlichi et al. and Cockcroft et al. are directed to the expression of Cyclin D proteins, but maintains that the references are relevant insofar as they teach the unpredictability of the effect of expressing a cell cycle regulatory protein on controlling or altering growth characteristics in a plant.

Applicants finally argue that undue experimentation would not be required to practice the claimed invention, as the specification provides ample direction with respect to the isolation of CKI genes, vector construction, and targeting of phenotypic effects to specific plant parts and plant tissues via the selective use of promoters (reply page 18).

The Office maintains that it would require undue experimentation to practice the claimed invention because the specification does not provide sufficient guidance for skilled in the art to determine which nucleic acids encoding a CKI to express in a transgenic plant in order to obtain the desired phenotypes, as Applicants have disclosed the phenotypic effect of expressing only one nucleic acid encoding a CKI, the nucleotide sequence of SEQ ID NO:1 that encodes the polypeptide of SEQ ID NO:2. Direction with respect to the isolation of CKI genes, vector construction, and targeting of phenotypic effects to specific plant parts and plant tissues via the selective use of promoters does not provide guidance with respect to the selection of the appropriate polynucleotide to express in the plant to obtain the desired phenotypes, as one skilled in the art would require direction as to what functional domains would be required in a polypeptide encoded by the appropriate polynucleotide.

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The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 2.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "increasing the level of cyclin-dependent kinase inhibitor", because "increasing" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 5.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 5.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 7.

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 11.

The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 14.

The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 15.

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The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "increasing stomata size", because "increasing" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 17.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 17.

The rejection of claim 18 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "increasing gas exchange and photosynthesis", because "increasing" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 18.

The rejection of claim 18 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 18.

The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 19.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 21.

The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 25.

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The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "facilitating", is withdrawn in light of the amendment of claim 27.

The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 27.

The rejection of claim 30 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 30.

The rejection of claim 31 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 31.

Claim 36 remains rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "essentially" and "derived thereof". Amendment of the claim to recite that "variety derived thereof with essentially the same characteristics" does not overcome the rejection, because it is still unclear what would be derived from the transgenic plant and what would be retained by the transgenic plant. It is suggested that the claim be amended to recite "obtained" rather than "derived" in order to overcome the rejection.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "essentially the same characteristics". It is unclear what characteristics of the

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transgenic plant are being referred to, as any transgenic plant has numerous characteristics in addition to the transgene, such as flower color, disease resistance, etc.

The rejection of claim 46 under 35 U.S.C. 112, second paragraph, as being is indefinite in the recitation of "wherein the cells have a decreased ploidy level", because "decreased" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 46.

The rejection of claim 48 under 35 U.S.C. 112, second paragraph, as being is indefinite in the recitation of "wherein the total cell number of the plant is decreased", because "decreased" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 48.

The rejection of claim 49 under 35 U.S.C. 112, second paragraph, as being is indefinite in the recitation of "comprising cells of increased size", because "increased" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 49.

The rejection of claim 49 under 35 U.S.C. 112, second paragraph, as being is indefinite in the recitation of "having increased photosynthetic capacity", because "increased" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 49.

The rejection of claim 50 under 35 U.S.C. 112, second paragraph, as being is indefinite in the recitation of "comprising leaves with increased stomata size", because "increased" is a relative term lacking a comparative basis, is withdrawn in light of the amendment of claim 50.

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Claims 2, 5, 7, 11, 14-15, 17-19, 21, 25, 27, 30-31, 36, 56 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "interacts with CDC2a". The nature of the interaction between the CKI and CDC2a is unclear, as proteins may interact in a variety of different ways, such as by binding, phosphorylation, etc.

Claim Rejections - 35 USC § 101

The rejection of claims 56 and 57 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in light of the amendment of claims 56 and 57.

Claim Rejections - 35 USC § 102

The rejection of claims 2, 5, 7-25, 27-31, 36-51 and 56-57 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 99/64599 (16 December 1999, Applicant's IDS) is withdrawn in light of Applicant's assertion that the instant application claims the benefit of priority from earlier filed applications, and in view of copies of the priority documents provided.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
October 19, 2002


PHUONG T. BUI
PRIMARY EXAMINER